

Why is this study being done?

The purpose of this study is to test the safety, side effects, and how well a potential new medicine works.

The study will help answer the following questions:

- What are the side effects of the study medicine?
- Can the study medicine help children with LMs?

Who can participate in the STARBORN-1 Study?

Children who meet the criteria below may be eligible to join the study:

- 6 months to less than 18 years of age
- LM in the head, neck, or area of the chest between the lungs

Support for participants

- There is no cost to you for the study medicine, doctor visits, or tests that are part of this study.
- You will be compensated for your time with a set amount for each visit completed.
- Your travel expenses may be paid for by the study sponsor.
- You will be able to book transportation through a travel concierge and have it paid for directly by the study sponsor.

Thank you for your interest in this important research study.

The STARBORN-1 Study is a medical research study at children's hospitals and clinics in the US. Doctors are studying a potential new medicine for lymphatic malformations.

Study participation is 100% your choice. Even after joining the study, you or your child can change your mind at any time for any reason.

If you are interested in learning more about this study, please contact:



Scan the code or visit
www.Starborn1study.com.

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STARBORN-1 Study

A research study for children
with lymphatic malformations

Study Overview



What happens during the STARBORN-1 Study?

Your child will be in the study for up to 54 weeks and will have to visit the hospital/clinic about 8 times.

SCREENING PERIOD

STUDY TREATMENT PERIOD

FOLLOW-UP PERIOD

Your child will receive up to 4 doses of the study medicine. Each dose will be about 6 weeks apart.

After this, your study doctor may discuss additional doses with you if your child could possibly benefit.

What kinds of tests and procedures will there be?

Your child's well-being is the number one priority. The study doctor will check your child's health for safety and to see how well the study medicine works.



HEALTH REVIEW



PHYSICAL EXAM



HEART TEST



IMAGING



ULTRASOUND



BLOOD TESTS



QUESTIONNAIRES



STUDY MEDICINE INJECTION



For 14 days after each injection, you'll use an app to report your child's temperature and any reactions or side effects.

What is the study medicine?

The study medicine is injected into a target cyst in the LM. It is designed to start an immune response that shrinks the target cyst.

The study medicine is similar to a medicine that has been used in other countries to treat LMs and other conditions for over 20 years.

Children participating in this study will be some of the first children in the United States to receive the study medicine to treat LMs. The study medicine is not yet approved by the United States Food & Drug Administration (FDA).

